C.S. B3: A Provider Intervention Involving Written Questionnaires and an Educational Conference

Overview

This study randomizes primary care providers into three groups in order to evaluate three clinical reminder modes for lipid management in patients with heart disease.

Subjects & Sample Size

Subjects are primary care providers at six VAMCs.

Data Collection

Physicians will participate in an educational conference regarding prescribing practices and the use of clinical reminders, and then will be randomized to three groups that will work with three different clinical reminder systems (patient-directed mailed reminders, computer/chart reminders, and automatic consults).

Questionnaires will gather information about the providers' experiences with the educational intervention and the reminder systems being evaluated.

Identifying information retained for follow-up is stored separately from collected data, which is entered into a database without identifying information. All electronic data sets are maintained in password protected files. Study documents are stored in a locked cabinet.

Questions:

1. Is a waiver of informed consent or written informed consent appropriate? [*Link*]

2. Is a waiver of HIPAA authorization appropriate? [*Link*]

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[From OHRP Web site: www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm]

1. Is a waiver of informed consent or written informed consent appropriate?

Chart 10: Can informed consent be waived or consent elements be altered under 45 CFR 46.116(c) or (d)?

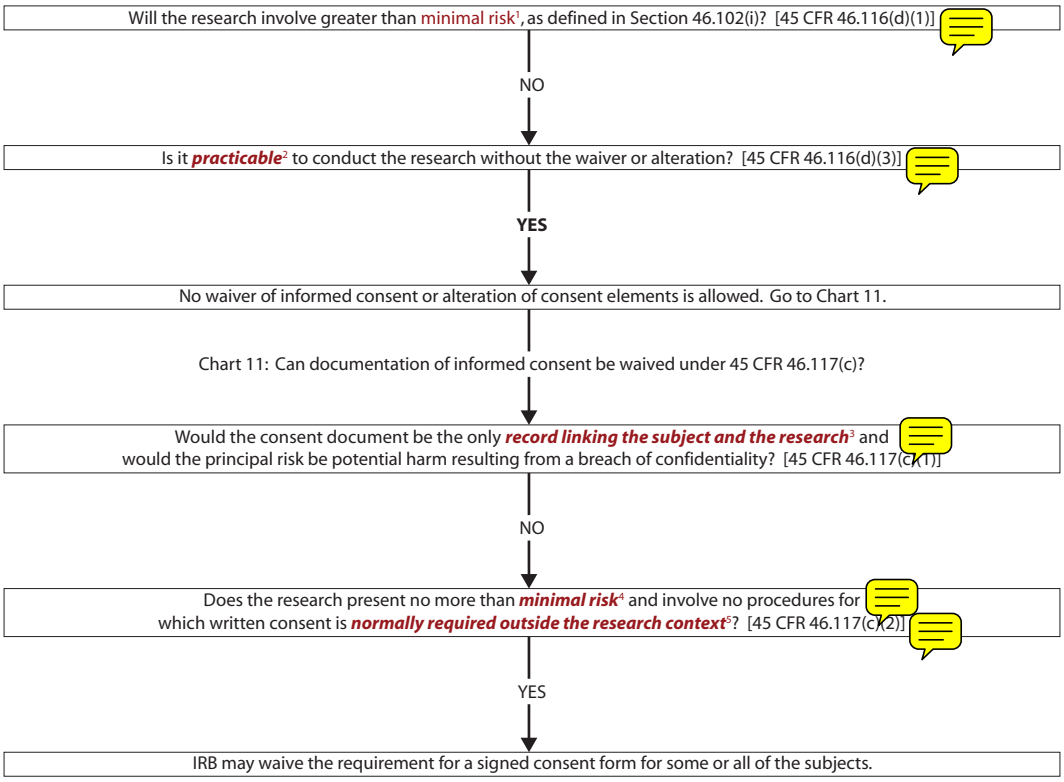

Chart 11: Can documentation of informed consent be waived under 45 CFR 46.117(c)?

Notes for C.S. B3: Q1

[1]**Definition:** "Minimal risk means that the ***probability*** and ***magnitude*** of harm or discomfort anticipated in the research are not greater in and of themselves than those ***ordinarily encountered in daily life*** or during the performance of routine physical or psychological examinations or tests" (CFR 46.102(1)).

Discussion: The majority of the panel members felt that this study is minimal risk. The major risk to the physician of participating in this study is potential loss of confidentiality. (Randomization to one of the three study groups does not pose any risk.) The panel felt that the ***probability and magnitude*** of harm from loss of confidentiality are no greater than ***that which is encountered in daily life***. With the appropriate safeguards, the likelihood of a breach in confidentiality is very low. Even if confidentiality of the research data was breached, negative comments made as part of a research study are likely to result in much less retribution than negative comments made in a public forum; and physicians routinely comment on organizational practices in public forums.

Three of the panel members felt that the study could potentially be greater than minimal risk, because of the potential for jeopardizing the participants' employment if they commented negatively on the intervention (or some other aspect of their work place) and there was a breach in confidentiality. In considering the probability of a breach in confidentiality, the IRB must look not only at the safeguards in place for storing data, but also how the data will be reported. If the sample size at a site is particularly small, it may be easy to ascribe data (comments) to a particular provider based on various characteristics of the respondents included in the reported findings.

[2]**Definition:** It is practicable to obtain informed consent, because someone from the study team will need to enroll each participant and describe the study to them.

[3]**Definition:** The investigators are maintaining a file of identifiers that can be linked to the subjects.

[4]**Definition:** "Minimal risk means that the ***probability*** and ***magnitude*** of harm or discomfort anticipated in the research are not greater in and of themselves than those ***ordinarily encountered in daily life*** or during the performance of routine physical or psychological examinations or tests" (CFR 46.102(1)).

Discussion: The majority of panel members considered this study to be minimal risk. However, three members thought the study had the potential to be greater than minimal risk. See discussion for note #1.

[5]**Discussion:** The majority of the panel felt that the study involved no procedures for which written consent is normally required outside the research context. That is, written consent is not normally required for obtaining provider feedback on new information systems or educational activities.

2. Is a waiver of HIPAA authorization appropriate?

Yes. The majority of the panel felt that a waiver of HIPAA authorization is appropriate, because no health information is being collected on the participating physicians.